

REMARKS**Amendments to the Specification**

Figures 1 and 6 and the Brief Description of the Drawings have been amended to insert the appropriate SEQ ID NOs. Accordingly, a revised sequence listing is also provided to include all of the SEQ ID NOs designated in the specification. No new matter has been added.

Page 21 of the specification has been amended to provide reference to the correct figure numbers. No new matter has been added.

The abstract originally filed in the corresponding PCT application has been added at page 26. No new matter has been added.

Amendments to the Claims

Claims 1-13 and 23-25 were pending. Claims 5, 6, 9, 23, and 24 have been canceled without prejudice. Claims 1-4, 7, 8, 10, 11, 13 and 25 have been amended. Support for the foregoing amendments can be found as follows in the specification as originally filed.

Claims 1-4	Page 9, lines 19-16; page 10, lines 16-26
Claims 7, 8, and 10	Page 9, lines 19-16; page 10, lines 16-26
Claim 11	Page 17, lines 2-6
Claim 13	Page 17, lines 7-10
Claim 25	Page 17, lines 20-27

No new matter has been added. The foregoing amendments have been made solely to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Rejection of Claims 1-13 and 23-25 Under 35 U.S.C. §112, First Paragraph

Claims 1-13 and 13-25 are rejected as not meeting the written description requirement. The Examiner specifically states that the

claimed genus of polynucleotides encompasses potentially a large number of DNA fragments of various sizes (≥ 261) and from different animal species, wherein said DNA fragments can be derived from either 5' or 3' of the GDF-9 gene, or from the intron of said gene. Such recitation also encompasses DNA sequences share a certain homology with any 261 or bigger DNA fragment from either 5', 3' or the intron of the GDF-9 gene, wherein said DNA may not even have a regulatory function.

The Examiner further states that

[t]he specification only discloses a 10 kb fragment immediately 5' from the transcription site of the mouse GDF-9 gene that directs transcription of GFP in mouse ovary, and a 3.3 kb fragment immediately 5' from the transcription start site of the mouse GDF-9 gene that directs transcription of GFP in mouse ovary and testis. The specification does not describe a regulatory element of any size in any other non-human animal that can direct testis or ovary specific gene transcription. The specification also fails to describe any fragments larger than 261bp isolated from either 5' or 3' of the mouse GDF-9 gene or in any intron of the GDF-9 gene that can direct ovary or testis specific transcription. Furthermore, the specification fails to teach what are the necessary elements these fragments must share to be functional as direct tissue specific expression in ovary or testis. As such, the structural functional relationship is missing

The Examiner also considers claims which specify that the claimed polynucleotide be derived from "the 10 kb of DNA" or derived from "the 3.3 kb to 10 kb of DNA" which is "immediately 5' of the transcription start site of a GDF-9 gene" also encompasses a large number of polynucleotides which is no described in the specification.

Applicants respectfully traverse this rejection. However, to expedite prosecution, the claims have been amended to be drawn to isolated polynucleotides and isolated regulatory elements which comprise a specific portion of a GDF-9 gene and a specific functional characteristic, *e.g.*, are capable of regulating expression of an operably linked gene in oocytes and/or testis. Based on Applicants' teachings (as described in detail below) and the level of skill in the art, the present specification shows that Applicants were in possession of the claimed invention.

For example, Applicants' disclosure provides a detailed description of how to identify and characterize the claimed GDF-9 molecules from variety of sources including mammalian and avian genomic cDNA libraries or synthesized from a variety of known and sequenced GDF-9 genes (see, *e.g.*, page 9, line 19 through page 13, line 29). Applicants further teach methods for preparing expression vectors which comprise the identified regulatory elements, as well as

methods for transfecting cells with such vectors (see, *e.g.*, page 14, line 1 through page 16, line 29). Further, the specification provides working examples which demonstrate how to the claimed molecules can be tested for regulating expression of genes as claimed (see, *e.g.*, page 19, line 6 through page 22, line 4).

Based on at least the foregoing and the high level of skill in the art, the Examiner has failed to show by a preponderance of the evidence why a person skilled in the art would not recognize in Applicants' disclosure a description of the claimed invention.

Rejection of Claims 1-3, 7-13 and 23-25 Under 35 U.S.C. §112, Second Paragraph


Claims 1-3, 7-13 and 13-25 are rejected as being indefinite based on the word "derived." Applicants respectfully traverse this rejection. However, to expedite prosecution, the amended claims do not include the word "derived." Therefore, this rejection is now moot.

SUMMARY

Applicants respectfully submit that the above-identified application is in condition for allowance. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

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Respectfully submitted,

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